Operator's Manual

#327

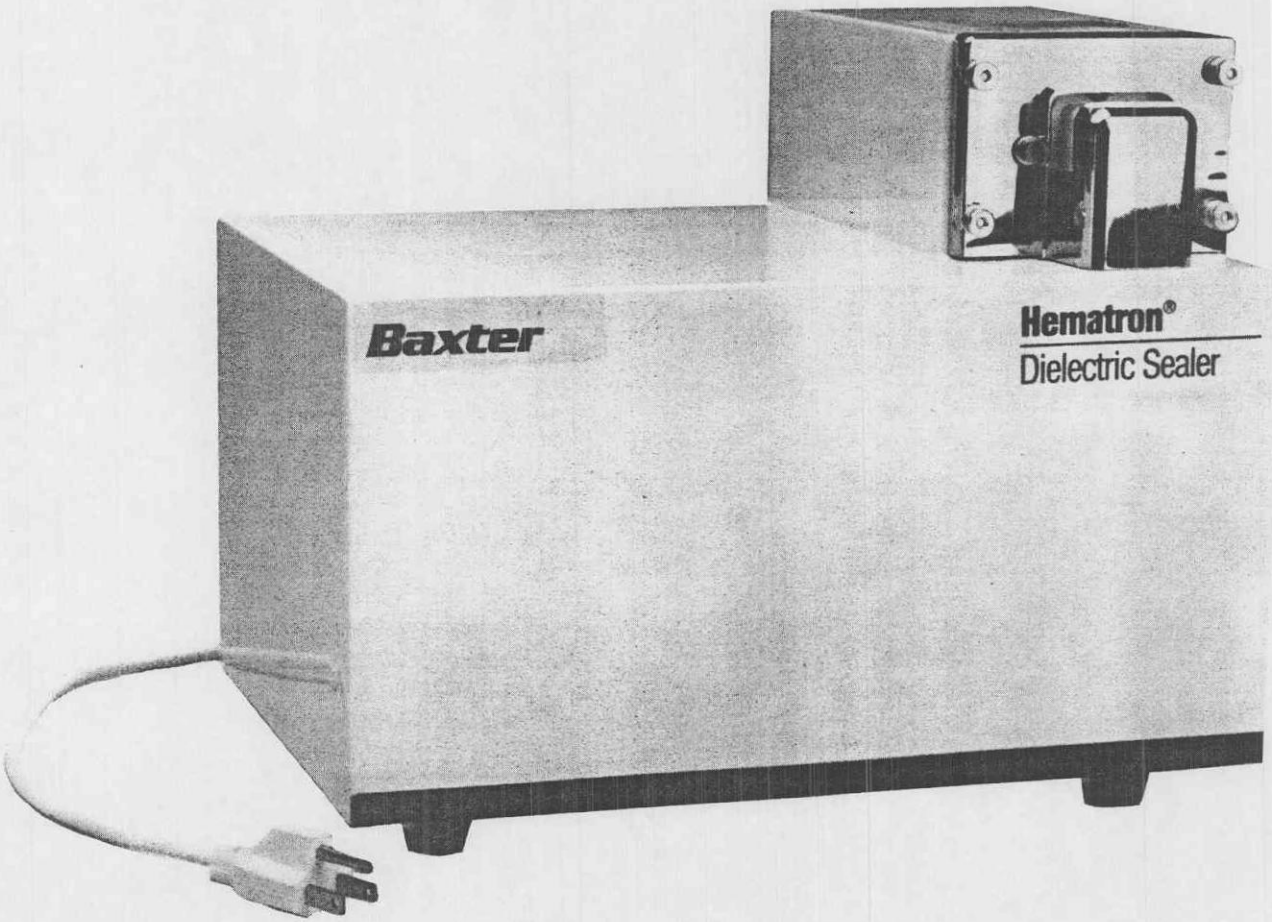
Fenwal®

Hematron® Dielectric Sealer

4R4330/4R4340

Baxter

Hematron® Dielectric Sealer



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1.0 General Information

1.1 Introduction

This manual contains operation and routine maintenance information for the 4R4330 and 4R4340 Hematron® Dielectric Sealers from Baxter Healthcare Corporation.

1.2 Description

The Hematron® Dielectric Sealer is an electronic device designed to automatically produce hermetic, snap-apart seals in Blood-Pack® Unit tubing. Seals are made by placing the tubing in the sealer head and depressing a trip switch. Segments may be formed by advancing the tubing through the sealer head to produce a series of seals.

The 4R4330 operates on 115 VAC 50-60 Hz input power and the 4R4340 operates on either 115 VAC or 230 VAC 50-60 Hz input power. Heat range may be selected to provide sealing intensity appropriate to tubing wall thickness and line voltage. See Table 1-1 for specifications.

Table 1-1 Specifications

Parameter	Value/Description
Listing	4R4330: CSA, UL, FCC Grant of Certification, Section 18.125
Input Voltage	4R4330: 115 VAC 4R4340: 230 VAC
Input Frequency	50/60 Hz
Input Power	150 Watts maximum
Input Current	4R4330: 1.2 Amperes 4R4340: 0.6 Amperes
Dielectric Strength	Greater than 1,000 VAC
Fuse	2 Amperes, Type 3AG SB
Dimensions	24.1 cm H x 23.5 cm D x 31.1 cm W (9½" x 9¼" x 12¼")
Weight	8.5 kg (18.75 lb)
RF Frequency	40.68 MHz Nominal
Maximum Tubing Size	3.9 mm (0.153") Inside Diameter, 0.5 mm (0.02") Wall Thickness
Power Cord	Three Wire SVT 18 Gauge (AWG) 2.4 m (8 ft) Long with Attached Molded Plug
Storage Humidity	0% to 95% Relative Humidity, Non-Condensing
Storage Temperature	30°F to 140°F

1.3 Accessories

A splash shield that mounts over the sealing head is available:
Code 4R4331 splash shield for Hematron® Dielectric Sealer, 100 units per case.

2.0 Operation

This section contains instructions for the installation, operation and routine maintenance of the Hematron® Dielectric Sealer. Read all instructions carefully before using the unit.

2.1 Unpacking

Each Hematron® Dielectric Sealer is shipped completely assembled and ready to operate. Inspect unit immediately upon receipt and report any defects or damage to the freight carrier within 24 hours and your local Fenwal representative.

2.2 Installation

Operation of the Hematron® Dielectric Sealer is controlled by three controls on the rear panel of the unit (see Figure 2-1).

A 115/230 Voltage Selector Switch—Selects voltage corresponding to line output. On the 4R4330 this switch is permanently set in the 115 VAC position.

B On/Off Power Switch—Controls AC power to unit.

C Heat Control—Adjusts RF power level to sealer head.

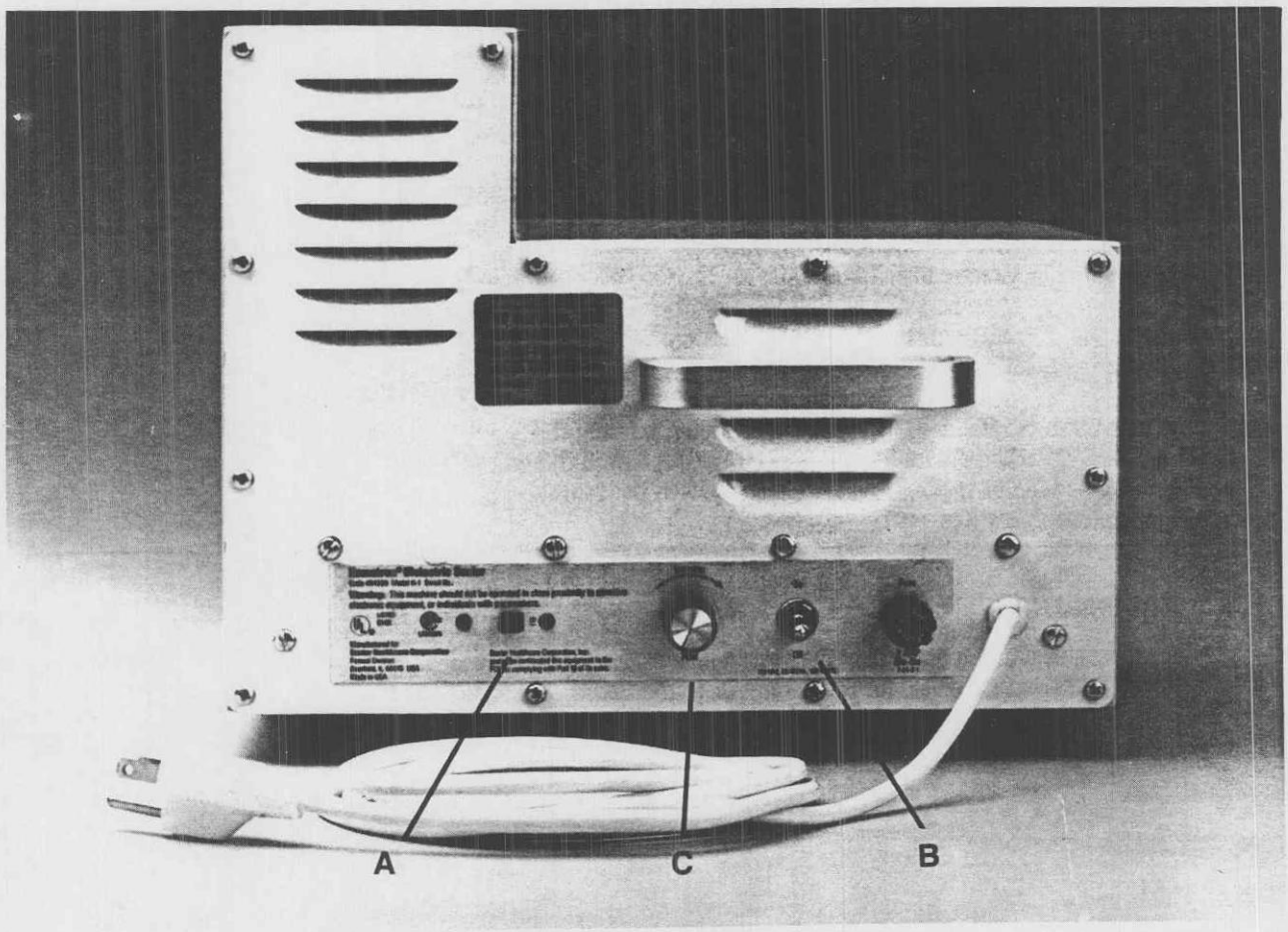

Figure 2-1 Hematron® Dielectric Sealer, Rear View

Caution: On the 4R4340, before connecting power cord to electrical outlet, be certain that the 115/230 Voltage Selector Switch is set to match local line voltage. The switch is held in position by two retaining screws and a guard. To change the switch setting, loosen the retaining screws, slide the switch and guard to new position, and retighten the screws.

2.3 Operating Instructions

Warning: This machine emits a low level of electromagnetic (nonionizing) radiation while sealing. It should not be used or repaired by individuals with pacemakers. It should not be used near sensitive electronic equipment.

1. Set On/Off Power Switch to On. Illuminated pilot light on the sealing head indicates that power to the unit is on.
2. Set Heat Control at 2 o'clock position.

Note: If line voltage is low [90 to 100 volts for 115 VAC nominal line (4R4330, 4R4340) or 180 to 200 volts for 230 VAC nominal line (4R4340)] rotate Heat Control fully clockwise.

3. Allow at least two minutes for Hematron® Dielectric Sealer to warm up before using.
4. Place Blood-Pack® Unit on top of Hematron® Dielectric Sealer. Wipe tubing dry if moisture is present.
5. Position tubing so that the x mark nearest the needle is between the sealing jaws. Gently depress tubing to trigger the sealing process. Hold tubing in place until the sealing jaws open (see Figure 2-2).

Note: Opening of the sealing jaws indicates completion of the sealing process. The result is a hermetic seal of the tubing. After waiting 3 or more seconds to allow the tubing to cool, segments can be separated at the seal by twisting or snapping the tubing apart.

Caution: Do not touch sealing jaws during operation. A burn may result if direct skin contact is made while sealing.

6. Move tubing to next x mark and repeat sealing process as required.
7. Turn off power to Hematron® Dielectric Sealer when it is not in use continuously.

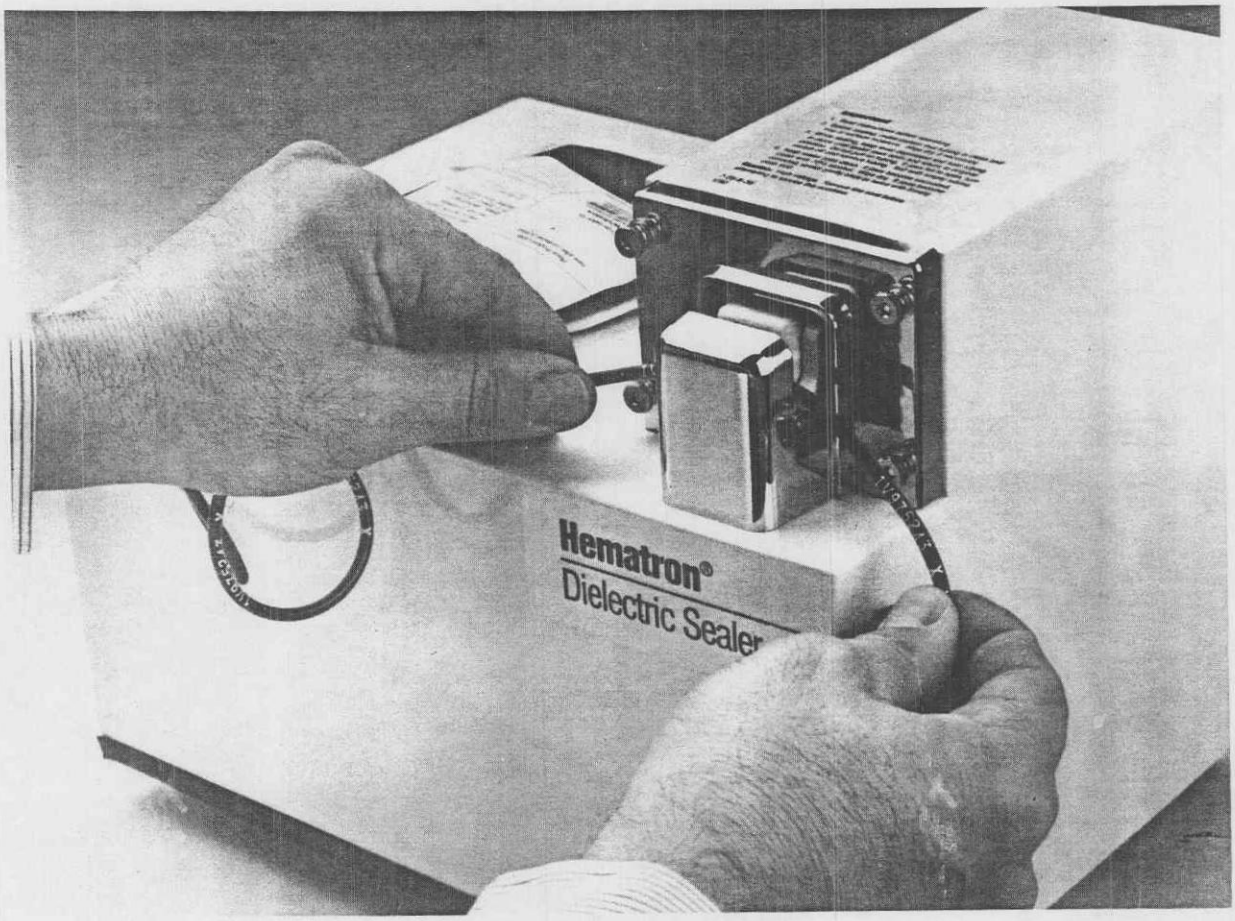

Figure 2-2 Sealing Tubing

2.4 Routine Maintenance

The Hematron® Dielectric Sealer should be cleaned daily after use. If spills occur, the unit should immediately be removed from service and cleaned completely before resuming use.

Caution: Blood and blood products should be treated as potentially infectious at all times. In the event of blood spills, appropriate protective clothing should be worn during cleanup procedures. After removing residual biological material, surfaces which have been in contact with blood or components should be disinfected using a chemical germicide considered as a "sterilant" by the Environmental Protection Agency (EPA). Alternatively, a freshly prepared solution of diluted sodium hypochlorite (household bleach) may be used to disinfect surfaces which will not be harmed by the solution. Diluted solutions ranging from 1 part bleach in 10 parts water to 1 part bleach in 100 parts of water may be used. Regardless of the sterilant or disinfection solution used, remember to remove any residue by rinsing with water (and drying) to ensure that surfaces of the equipment are not subject to corrosion or discoloration. Discard all materials in contact with blood according to institutional policies regarding disposal of biohazardous materials. (Reference: Recommendations for Prevention of HIV Transmission in Health-Care Settings. Morbidity and Mortality Weekly Report (Supplement) Volume 36, Number 25, August 21, 1987.)

Caution: Disconnect unit from power source before performing any maintenance procedure.

2.5 Sealer Head Cleaning

Caution: The Hematron® Dielectric Sealer is equipped with an external electromagnetic interference (EMI) shield. To minimize the possibility of interference with other electronic devices, this shield must be in good condition and properly installed whenever the Hematron® Dielectric Sealer is operated.

Access to the sealer head may be gained by removing the four thumbnuts and washers, which attach both the clear plastic splash shield and the EMI shield to the cabinet, and removing the shields.

Note: Do not misplace the flat washers used with the thumbnuts. They must be used during reassembly (see Figure 2-3).

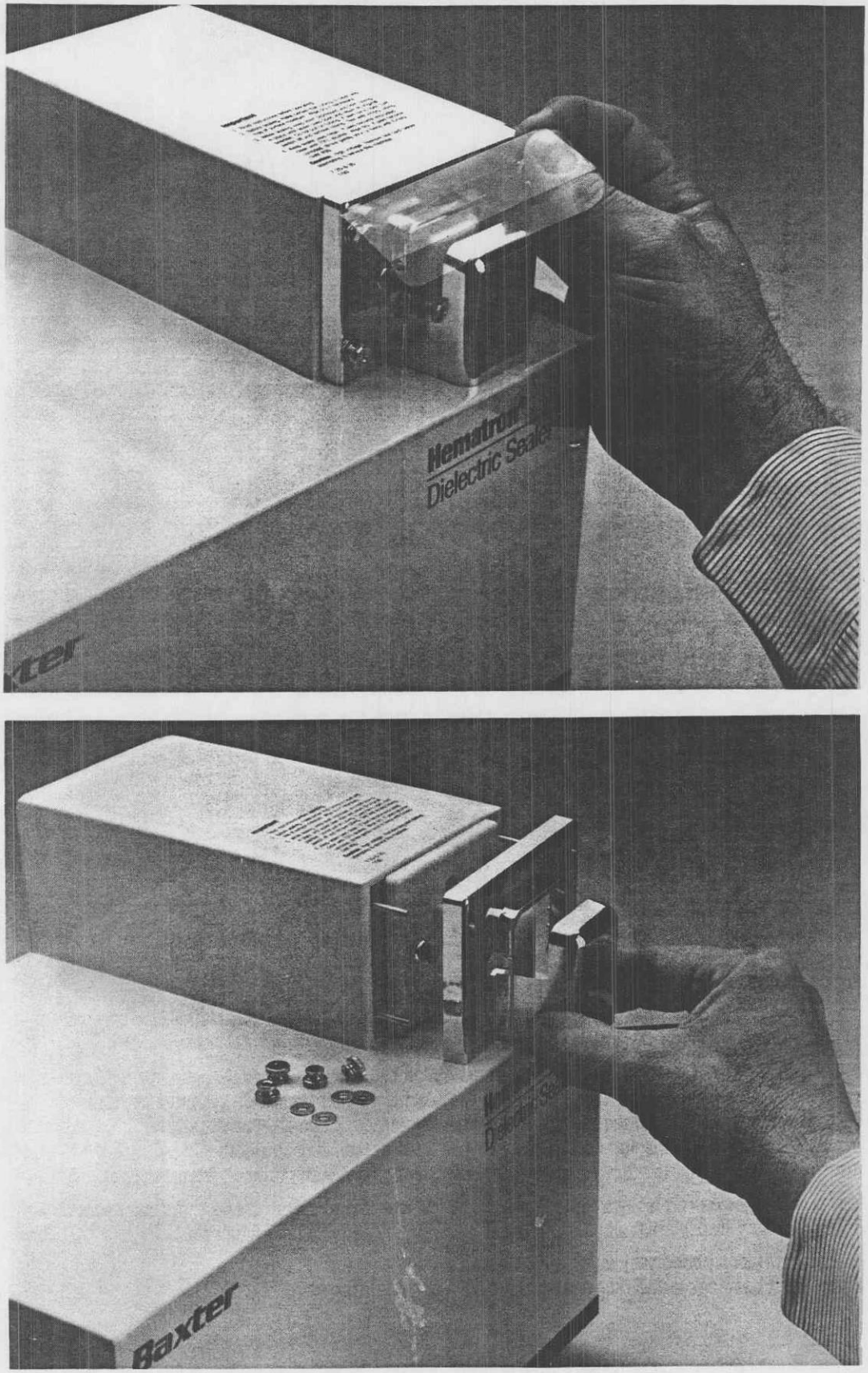

Figure 2-3 Splash Shield and Electromagnetic Interference Shield Removal

1. Clean the jaw surfaces of the sealer head gently but thoroughly with a mild detergent or 70% alcohol solution using a swab or small stiff-bristled brush (see Figure 2-4). Wipe the jaws completely dry with a cotton swab or paper towel.

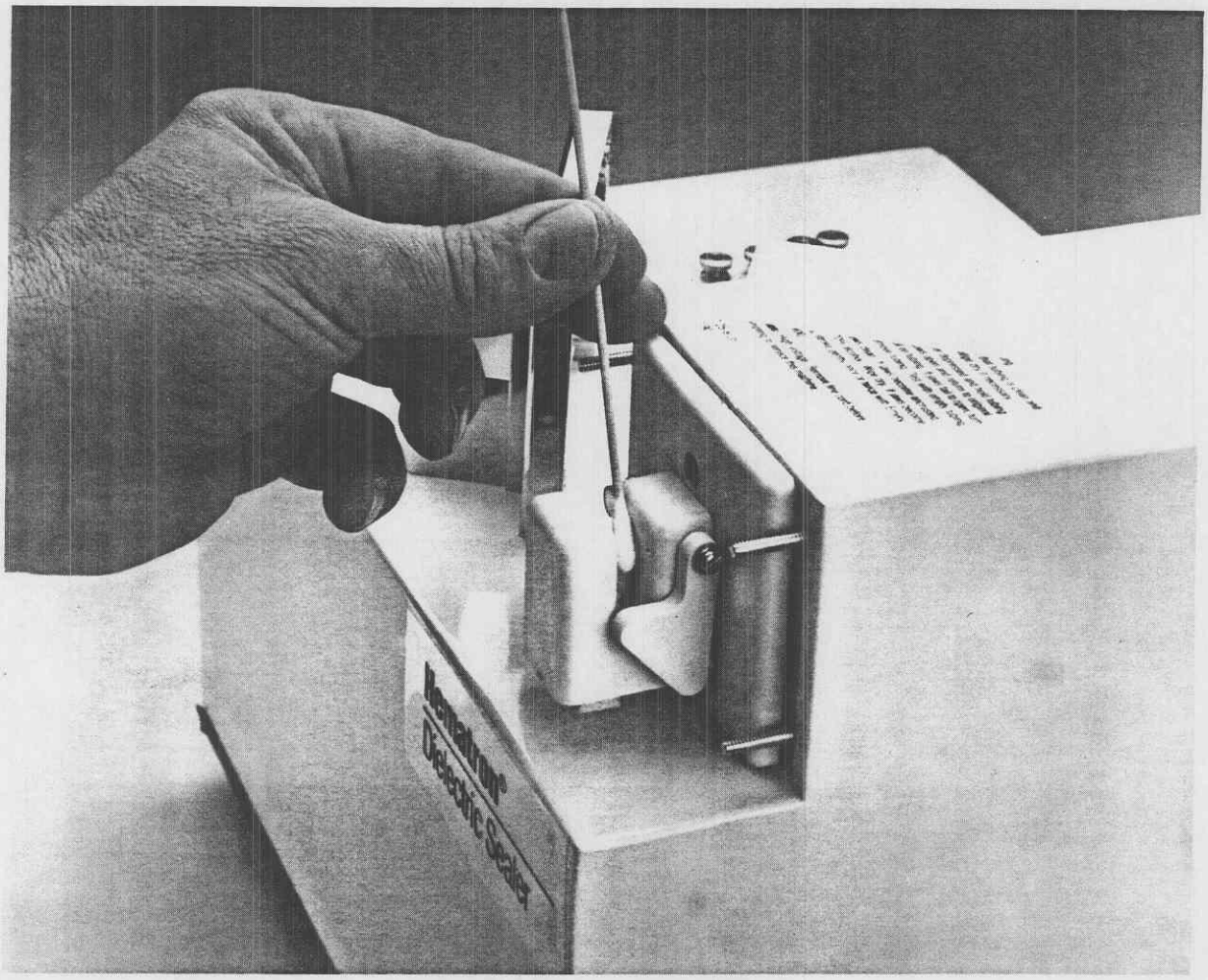

Figure 2-4 Sealer Head Cleaning

2. If the sealer jaws have become pitted, clean them using #00 emery cloth. Sand the pitted surface in such a manner as to remove the surface roughness, and clean any resulting debris from the sealer head according to the head cleaning procedure.
3. Clean the splash shield with a mild detergent or 70% alcohol solution using a soft cloth. Use care with this shield, as contact with abrasive materials will cloud or scratch the surface. Dry with a soft, lint-free cloth.
4. Inspect the sealer head EMI shield for surface contamination or corrosion. Contamination or mild corrosion should be removed by using the cleaning methods outlined in the head cleaning procedure. Do not attempt to use abrasives to remove contaminants as this will result in removal of the electroplated coating of the shield. If corrosion is present that cannot be removed by cleaning, or if the shield has been broken, the shield should be replaced before the Hematron® Dielectric Sealer is returned to service. Replacements may be ordered from the Fenwal Service Center.
5. After any necessary cleaning is completed, replace the EMI shield and splash shield and secure them with the four thumbnuts. Be sure to use a flat washer under each thumbnut, and use only finger pressure when tightening them.
6. Clean cabinet surfaces periodically using a cloth moistened with water or a mild detergent. Do not allow liquid to flow through the vent openings in the rear panel. Dry with a soft, lint-free cloth.

2.6 FCC Requirements

The Hematron® Dielectric Sealer is designed and manufactured to comply with the rules of the United States Federal Communications Commission (FCC), Title 47, Part 18 of the Code of Federal Regulations. It has been prototype certificated to the FCC as complying with these regulations.

3.0 Warranty and Service

3.1 Warranty

Baxter Healthcare Corporation, Fenwal Division, (Fenwal) warrants that the equipment shall be free from defects in material and workmanship when delivered to the original purchaser. Fenwal's sole obligation shall be limited to repair or replacement, at Fenwal's option and expense, of the defective part or unit for a period of one (1) year following the date of initial delivery.

The warranty extends only to the original purchaser and is not assignable or transferable, and shall not apply to auxiliary equipment, disposable accessories, or light sources.

FENWAL WARRANTS THAT THE EQUIPMENT IS FIT FOR THE PURPOSES AND INDICATIONS DESCRIBED IN THE LABELING WHEN USED IN ACCORDANCE WITH THE DIRECTIONS FOR USE. UNLESS THE EQUIPMENT IS USED IN ACCORDANCE WITH SUCH INSTRUCTIONS, THIS WARRANTY IS VOID AND OF NO EFFECT. NO OTHER EXPRESSED OR IMPLIED WARRANTY EXISTS, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. FENWAL'S SOLE OBLIGATION AND PURCHASERS EXCLUSIVE REMEDY FOR BREACH OF WARRANTY SHALL BE LIMITED TO REPAIR OR REPLACEMENT AT FENWAL'S OPTION. FENWAL SHALL NOT BE LIABLE FOR PROXIMATE, INCIDENTAL, OR CONSEQUENTIAL DAMAGES. MODIFICATIONS, ALTERATIONS, RECALIBRATIONS OR ABUSE, AND SERVICE BY OTHER THAN A FENWAL AUTHORIZED REPRESENTATIVE MAY VOID THE WARRANTY.

3.2 Service Information

While under Fenwal Warranty, the instrument must not be opened by unauthorized personnel.

All repairs must be done by qualified personnel only, and must follow procedures given in the Service Manual.

Contact Fenwal's Product Service Division for service and repair information for all instruments. In USA call (800) 323-9098 (toll free) or in Illinois, (708) 948-4590. Outside of USA, contact your local Fenwal Product Service Division representative.

Shipping cost for all units returned to Fenwal shall be paid by the customer. **The unit must be packed in its original container or in another Fenwal approved container that will provide adequate protection during shipment.** To ensure prompt return, a Fenwal Product Service Division representative must be notified before shipping any unit for repair. When calling Fenwal's Product Service Division, please be prepared to provide code number and serial number of the unit. A service request number will be issued and should accompany all communications. A brief written description of the problem should be attached to the instrument when it is returned for service.

Fenwal Division will not be responsible for unauthorized returns or for units damaged in shipment due to improper packing.